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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA WOMEN'S HEALTH, INC., Plaintiff and Counter-Defendant, v. LUPIN LTD., LUPIN PHARMACEUTICALS, INC., WATSON LABORATORIES, INC. and WATSON PHARMACEUTICALS, INC. Defendants and Counter-Plaintiffs.	C.A. No. 2:10-cv-00080-FSH-PS C.A. No. 2:10-cv-01234-FSH-PS
TEVA WOMEN'S HEALTH, INC., Plaintiff and Counter-Defendant, v. MYLAN INC., MYLAN PHARMACEUTICALS INC., and FAMY CARE LTD. Defendants and Counter-Plaintiffs.	**DOCUMENT FILED ELECTRONICALLY** RETURN DATE: February 22, 2011

NOTICE OF APPEAL PURSUANT TO L.CIV.R. 72.1(c)
FROM MAGISTRATE JUDGE'S ORDER DENYING LUPIN'S
MOTION FOR LEAVE TO AMEND PATENT INVALIDITY CONTENTIONS

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PLEASE TAKE NOTICE that on February 22, 2011 at 9:00 a.m., or as soon thereafter as counsel may be heard, the undersigned attorneys for Lupin Pharmaceuticals, Inc. and Lupin, Ltd. (collectively, "Lupin") shall move before the Honorable Faith Hochberg, U.S.D.J., at the United States Post Office & Courthouse Building, 50 Walnut Street, Room PO 01, Newark, NJ 07101, to appeal Magistrate Judge Shwartz's Order denying Lupin's Motion for leave to amend Lupin's invalidity contentions to reflect an additional example of invalidity of U.S. Patent No. 7,615,545 pursuant to District of New Jersey Local Patent Rule 3.7 (see Document No. 136). A copy of Lupin's proposed Amended Invalidity Contentions is attached hereto as Exhibit "A."

PLEASE TAKE FURTHER NOTICE that Lupin relies upon the accompanying Memorandum of Law in Support of Appeal from the Denial of Lupin's Motion for Leave to Amend Patent Invalidity Contentions, together with all papers currently on file with the Court and all papers and arguments Lupin may submit hereafter.

A Proposed Order is submitted herewith.

Respectfully submitted,

STERNS & WEINROTH, P.C.
Attorneys for Defendants,
LUPIN PHARMACEUTICALS, INC. and
LUPIN, LTD.

January 18, 2011

By: /s/ Karen A. Confoy_____

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the foregoing Notice of Appeal from the Denial of Lupin's Motion for Leave to Amend Patent Invalidity Contentions, supporting Memorandum and proposed Order were electronically filed with the Clerk of Court using CM/ECF on January 18, 2011, which will send notification to the registered attorneys of record that the document has been filed and is available for viewing and downloading.

By: /s/ Karen A. Confoy
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Attorney for Defendants
LUPIN PHARMACEUTICALS, INC. and
LUPIN, LTD.

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA WOMEN'S HEALTH, INC., Plaintiff/Counterclaim-Defendant, vs. LUPIN, LTD., LUPIN PHARMACEUTICALS, INC., WATSON LABORATORIES, INC. and WATSON PHARMACEUTICALS, INC. Defendants/ Counterclaim-Plaintiffs.	Civil Action No. 2:10-cv-00080-FSH-PS Civil Action No. 2:10-cv-01234-FSH-PS Judge Faith S. Hochberg Magistrate Judge Patty Shwartz
TEVA WOMEN'S HEALTH, INC., Plaintiff, vs. MYLAN INC., MYLAN PHARMACEUTICALS INC. and FAMY CARE LTD. Defendants	**LUPIN'S FIRST AMENDED INVALIDITY AND NON-INFRINGEMENT CONTENTIONS**

PRELIMINARY STATEMENT

The Defendants, Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"), by their undersigned attorneys, submit the following Invalidity and Non-Infringement Contentions pursuant to Local Patent Rules 2.2, 3.3 and 3.6.

Lupin reserves all of its rights to supplement, amend and modify the contentions made herein, with respect to the claims of U.S. Patent No. 7,615,545 ("the '545 patent"), including

contentions with respect to alleged "secondary considerations," in light of Plaintiff's contentions, Plaintiff's proposed claim constructions and future discovery.

I. THE RELEVANT CLAIMS OF THE '545 PATENT ARE ANTICIPATED UNDER 35 U.S.C. § 102

In light of the discovery Lupin has received, in addition to the bases set forth in response to other interrogatories, in Lupin Ltd.'s November 24th, 2009 letter, and in Lupin's June 7, 2010 contentions, Lupin contends that claims 19, 1, 2, 4-9, 15, 17, 18 and 20-21 are anticipated under 35 U.S.C. § 102(a) and (b) by German Published Patent Application No. DE 19525017 A1 ("DE '017"). DE '017 is the foreign priority patent application for U.S. Patent No. 6,027,749 ("the '749 patent") and was published in German on January 2, 1997. DE '017 was not before the examiner during prosecution of the '545 patent.

DE '017 claims the same subject matter and discloses each and every element of claim 19 of the '545 patent. The claims of DE '017 require administration of estrogen/progestin (estrogen/"gestagen") for 84 consecutive days, followed by administration of unopposed estrogen for 7 consecutive days. DE '017 discloses that the "doses" should be oral formulations, such as tablets and pills. (DE '017 at p. 10, ll. 41-42.) The English translations of claim 1 and claim 3 of DE '017 are reproduced below.

> 1. *Two-stage pharmaceutical combined preparation for hormonal contraception* containing at least 30 daily unit doses, which preparation, *in its first stage, comprises as hormonal active ingredient a combination of an estrogen preparation and*, in a dose that is at least sufficient to inhibit ovulation, *a gestagen preparation, in a single stage form and, in the second stage comprises as hormonal active ingredient an estrogen preparation only*, wherein the first stage comprises a minimum of 25 and a maximum of 77 daily discrete or continuous unit doses and the *second stage comprises 5, 6 or 7 daily discrete or continuous unit doses*, and wherein the total number of daily units is equal to the total number of days of the desired cycle of a minimum of 30 and a maximum of 84 days.

> 3. Combined preparation according to claim 1 characterized in that *the first stage comprises* a minimum of 28 and a *maximum of 84 daily unit doses*.

DE '017 at p. 11 (emphases added).

Claims 9 and 10 of DE '017 expressly claim the same hormones and amounts as in claim 19 of the '545 patent:

> 9. Combined preparation according to any one of the preceding claims 1 to 8, characterized in that the *estrogen of the first stage is contained in each daily unit dose in a dose of*
> from 1.0 to 6.0 mg of 17β-estradiol,
> *from 0.015 to 0.025 mg of ethinyl estradiol*,
> from 1.0 to 4.0 mg of 17β-estradiol valerate
> and *the gestagen is contained in each daily unit dose in a dose of*
> from 1.0 to 3.0 mg of dienogest,
> from 0.05 to 0.075 mg of gestodene,
> *from 0.05 to 0.125 mg of levonorgestrel*,
> from 0.06 to 0.15 mg of desogestrel
> from 0.06 to 0.15 mg of 3-ketodesogestrel
> from 1.0 to 3.0 mg of drospironenone,
> from 1.0 to 2.0 mg of cyproterone acetate,
> from 0.2 mg to 0.3 mg of norgestimate,
> from 0.35 to 0.75 mg of norethisterone.
>
> 10. Combined preparation according to any one of the preceding claims 1 to 9, characterized in that *there is contained in each daily unit dose in the second stage an amount of*
> from 1.0 to 6.0 mg of 17β-estradiol,
> *from 0.002 to 0.04 mg of ethinyl estradiol*,
> from 1.0 to 4.0 mg of 17β-estradiol valerate.

DE '017, at pg. 12 (emphases added).

Claims 11, 13, 19 and 20 contain a parallel disclosure to claims 1, 3, 9 and 10 of DE '017 patent, except that they are directed to a contraceptive kit.

The specification of DE '017 also discloses that an especially preferred estrogen in the combination dosage is ethinyl estradiol and a preferred progestin is levonorgestrel. (DE '017 at p. 5, ll. 51-55.) In addition, it discloses that in an especially preferred embodiment, the unopposed estrogen dose is ethinyl estradiol from 0.01 to 0.015 mg in each daily unit dose. (DE

'017 at p. 5, ll. 50-51.) Thus, as 1 mg is equivalent to 1000 µg, DE '017 not only discloses each and every limitation of claim 19, but also highlights as preferred embodiments the specific dosages disclosed and claimed in the '545 patent.

The anticipating disclosure described in DE '017 is also fully enabled. *See In re Gleave*, 560 F.3d 1331, 1335 (Fed. Cir. 2009). DE '017 states that the formulation of the combined dosage can be prepared in a manner analogous to that already known for numerous conventional oral contraceptives, such as Microgynon®, which contains pills containing a combination of ethinyl estradiol/levonorgestrel. (DE '017 at p. 11, ll. 23-26.) Likewise, DE '017 discloses that the unopposed estrogen dosage can be prepared in a manner analogous to that known for estrogen-containing agents designed for oral administration that are already available, such as ProgynonC®. (DE '017 at p. 11, ll. 26-28.) It further states that "the formulation of the unit doses is effected in conventional manner with the use of auxiliaries known for the preparation of estrogen-/gestagen-containing and exclusively estrogen-containing tablets, pills, coated tablets, etc." (DE '017 at p. 10, ll. 41-42.) Because a person of skill in the art would have known how to make these commercially available oral contraceptive formulations, DE '017 is an enabling reference. If a reference both "discloses all of the claim limitations and enables the 'subject matter that falls within the scope of the claims at issue,' the reference anticipates—no 'actual creation or reduction to practice' is required." *Gleave*, 560 F.3d at 1334 (quoting *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1380-81 (Fed. Cir. 2003)).

Thus, because DE '017 discloses all of the claim limitations of claim 19 and enables that subject matter, DE '017 anticipates claim 19 of the '545 patent. *See Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368 (Fed. Cir. 2005) (citing *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed. Cir. 1992)).

Because claim 19 is the narrowest asserted independent claim of the '545 patent, logic and case law dictate that DE '017's anticipation of claim 19 likewise renders all other asserted claims of the '545 patent invalid.[1] *See Minnesota Min. & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1299-1300 (Fed. Cir. 2002) (describing the inconsistency between a finding that an independent claim is not anticipated, but a dependent claim is anticipated: "While Schrödinger's cat may be both alive and dead at any given moment, even in theory, claim limitations cannot be concurrently both met and not met."); *King Pharms., Inc. v. Eon Labs., Inc.*, No. 2009-1437, 2010 WL 3001333 at *11 (Fed. Cir. 2010) (where an independent claim is anticipated, a claim that depends therefrom need only be evaluated on its "sole potential source of novelty"); *see also Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1319 (Fed. Cir. 2007) (obviousness). Accordingly, Lupin contends that claims 1, 2, 4-9, 15, and 17-21 are invalid as anticipated under 35 U.S.C. § 102(a) and (b).

II. THE RELEVANT CLAIMS OF THE '545 PATENT WOULD HAVE BEEN OBVIOUS UNDER 35 U.S.C. § 103

A. Claims 1, 2, 4-9, 15, and 17-21 would have been obvious to a person of ordinary skill in the art.

The '545 patent is entitled "Oral Contraceptives To Prevent Pregnancy and Diminish Premenstrual Symptomatology." Its earliest possible priority date is December 5, 2001, although the patent did not actually issue until November 10, 2009. Generally speaking, the '545 patent purports to claim a method of contraception comprising administration of a two-stage contraceptive regimen. In the first stage, which can last from 81 to 89 consecutive days, a combination of an estrogen called ethinyl estradiol (about 10-50 μg) and a progestin called

[1] A detailed claim chart for Lupin's invalidity contentions conforming to Pat. L. R. 3.3(c) is provided in Exhibit A.

levonorgestrel (about 50-150 μg) is administered. As noted in the '545 patent, this type of estrogen/progestin "combined oral contraceptive preparation" is "[t]he most prevalent form of oral contraception." '545 Patent col. 2 ll. 24-26. This stage is then followed by a second stage in which about 5-10 μg of "unopposed" estrogen—estrogen without any progestin—is administered for 2 to 8 consecutive days. Claim 1 is illustrative:[2]

> 1. A method of contraception in a female in need thereof, the method comprising administering to the female a dosage comprising a combination of estrogen and progestin for a period of 81 to 89 consecutive days, followed by administration of a dosage consisting essentially of estrogen for a period of 2 to 8 consecutive days,
>
> > wherein the estrogen that is administered in combination with progestin for the period of 81 to 89 day consecutive days is administered in a daily amount equivalent to about 10 μg to about 50 μg of ethinyl estradiol,
> >
> > the estrogen that is administered for the period of 2 to 8 consecutive days is administered in a daily amount equivalent to about 5 μg to about 10 μg of ethinyl estradiol, and
> >
> > the progestin that is administered for the period of 81 to 89 consecutive days is administered in a daily amount of about 50 μg to about 150 μg of levonorgestrel.

As described in its First Supplemental Response to Interrogatory No. 6, Lupin contends that German Published Patent Application No. DE 19525017 A1 ("DE '017") renders all of asserted claims of the '545 patent invalid as anticipated under 35 U.S.C. § 102. It was not before the examiner during prosecution of the '545 patent and is not cumulative to the '749 patent at least because it claims a contraceptive regimen with 84 daily doses of estrogen/progestin followed by 7 days of unopposed estrogen. Lupin further contends that all of the asserted claims

[2] Claim 1 is illustrative, but claim 19 is the narrowest applicable independent claim of the '545 patent. Therefore, Lupin's obviousness contention focuses on claim 19.

are invalid as obvious under 35 U.S.C. § 103 based on U.S. Patent No. 5,898,032 ("the '032 patent") in view of DE '017 or the '749 patent.

The '032 patent, which issued on April 27, 1999, disclosed the following:

> In accordance with the present invention, a women [sic] in need of contraception is administered *a combined dosage form of estrogen and progestin*, preferably monophasicly, for 60 to 110 consecutive days, *preferably about 80-90 days*, followed by an administration free interval of 3 to 10 days, preferably about 5-8 days, in which the daily amounts of estrogen and progestin are equivalent to about 5-35 mcg of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate, respectively. On a schedule of 84 days administration followed by 7 pill free days, there are only four treatment and menstrual cycles per year.
>
> The preferred estrogen and progestins are ethinyl estradiol and norethindrone acetate although other estrogens and progestins can be employed. . . . *The preferable amount of ethinyl estradiol is about 10-20 mcg and the preferable amount of the norethindrone acetate is about 0.25-1.5 mg.* Other estrogens vary in potency from ethinyl estradiol. For example, 30 mcg of ethinyl estradiol is roughly equivalent to 60 mcg of mestranol or 2,000 mg of 17 β-estradiol. Likewise, other progestins vary in potency from norethindrone acetate. *Thus, 3.5 mg of norethindrone acetate is roughly equivalent to 1 mg of levonorgestrel* or desogestrel and 3-ketodesogestrel and about 0.7 mg of gestodene.

'032 Patent, col. 3, l. 47-col. 4, l. 10 (emphases added). Thus, the preferred amounts disclosed in the '032 prior patent are 10-20 μg of ethinyl estradiol and 70-420 μg of levonorgestrel—both of which overlap with or encompass the amounts claimed in the '545 patent.[3]

DE '017 disclosed administration of a combination of estrogen and progestin for a variety of time periods, up to and including 84 days, followed by the use of unopposed estrogen for between 5 and 7 days. DE '017 also noted that ordinary pharmaceutical excipients may be used in making the hormone preparations. *See* DE '017, pg. 10, ll. 41-42.

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[3] The '545 patent and '032 patent disclose the same conversion factor for determining the amount of levonorgestrel that is equivalent to a given amount of norethindrone acetate. ('545 patent, col. 7, ll. 29-32.)

The specification of DE '017 described that an especially preferred estrogen in the combination dosage was ethinyl estradiol in an amount of 15-25 μg and a preferred progestin was levonorgestrel in an amount of 50-125 μg. (DE '017 at p. 5, ll. 30-36.) In addition, it described that in an especially preferred embodiment, the estrogen in the unopposed estrogen dose was ethinyl estradiol in an amount from 10 to 15 μg in each daily unit dose. (DE '017 at p. 5, ll. 50-51.) DE '017 thus guided one of skill in the art to use ethinyl estradiol and levonorgestrel in the amounts claimed by the '545 patent. The amount of ethinyl estradiol in the combination dose of claim 19 of the '545 patent is 20 μg, which falls squarely in the middle of the preferred range (15-25 μg) disclosed in DE '017. The amount of levonorgestrel in the combination dose of claim 19 is 100 μg, which also falls fully within the preferred range (50-125 μg) disclosed in DE '017. Finally, the preferred amount of ethinyl estradiol in the unopposed estrogen dose in claim 19 is 10 μg, which is also within the narrow preferred range (10-15 μg) of DE '017. Thus, DE '017 provided clear guidance to one of skill in the art to use the doses in the asserted claims of the '545 patent by describing them as preferred doses.

DE '017 provided motivation to use unopposed estrogen in this fashion by describing the benefits of administering 7 days of unopposed estrogen following 84 days of a combination estrogen/progestin hormone. DE '017 taught that such use of unopposed lower-dose estrogen, following these periods of administration of the described amounts of estrogen/progestin, provided *eight separate benefits* as compared to a comparable regimen lacking unopposed estrogen. *See* DE '017, at pg. 11, ll. 5-21.

In addition, Lupin contends that at least claim 19, as well as claims 1, 2, 4-9, 15, and 17, 18, 20 and 21 would have been obvious under 35 U.S.C. § 103 based on U.S. Patent No. 5,898,032 ("the '032 patent") in view of U.S. Patent No. 6,027,749 ("the '749 patent"). The '032 patent, which issued on April 27, 1999, disclosed the following:

> In accordance with the present invention, a women [sic] in need of contraception is administered *a combined dosage form of estrogen and progestin*, preferably monophasicly, for 60 to 110 consecutive days, *preferably about 80-90 days*, followed by an administration free interval of 3 to 10 days, preferably about 5-8 days, in which the daily amounts of estrogen and progestin are equivalent to about 5-35 mcg of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate, respectively. On a schedule of 84 days administration followed by 7 pill free days, there are only four treatment and menstrual cycles per year.
>
> The preferred estrogen and progestins are ethinyl estradiol and norethindrone acetate although other estrogens and progestins can be employed. . . . *The preferable amount of ethinyl estradiol is about 10-20 mcg and the preferable amount of the norethindrone acetate is about 0.25-1.5 mg.* Other estrogens vary in potency from ethinyl estradiol. For example, 30 mcg of ethinyl estradiol is roughly equivalent to 60 mcg of mestranol or 2,000 mg of 17 β-estradiol. Likewise, other progestins vary in potency from norethindrone acetate. *Thus, 3.5 mg of norethindrone acetate is roughly equivalent to 1 mg of levonorgestrel* or desogestrel and 3-ketodesogestrel and about 0.7 mg of gestodene.

'032 Patent, col. 3, l. 47-col. 4, l. 10 (emphases added). Using the conversion factor described above, the preferred amounts disclosed in the '032 prior patent were 10-20 µg of ethinyl estradiol and 70-420 µg of levonorgestrel—both of which overlap with or encompass the amounts claimed in the '545 patent.

Although the '032 patent did not disclose the use of unopposed estrogen during the second stage, the '749 patent disclosed exactly that. This prior art patent provided numerous examples in which, following administration of a combination of estrogen and progestin for a varying numbers of weeks, unopposed estrogen was administered for between 5 and 7 days. The '749 patent further taught that the extended period of administration of estrogen/progestin (or

estrogen/"gestagen," to use the '749 patent's language), coupled with a period of unopposed lower-dose estrogen, provided *eight separate benefits* as compared to a regimen lacking unopposed estrogen (like that disclosed in the '032 patent). *See* '749 Patent, col. 9, l. 33-col. 10, l. 4.[4] The '749 prior patent thus expressly taught those of skill in the art that they should modify an extended regimen of estrogen/progestin by adding a terminal week of unopposed estrogen.

While the '749 prior patent is inconsistent as to whether the extended period of estrogen/progestin administration is for a maximum of 77 or 84 days,[5] this inconsistency serves to underscore the fact that a person of skill in the art would have recognized the difference of a week or two to be unimportant. *See, e.g.*, Szarewski, *Contraception*, Oxford University Press 84-87 (1994) ("One of the advantages of being on the pill is that it is possible to alter the timing of your periods to suit yourself. You can either avoid a period altogether or postpone it to a more convenient time."). Thus, a person of ordinary skill would have understood from the '749 patent that a 7-day period of administering unopposed ethinyl estradiol, following either a 77-day or an 84-day period of estrogen/progestin administration, would be beneficial. This conclusion is supported by, among other things, the similarity between the dosages taught by the '749 and '032 prior patents.[6]

In light of the teachings of the prior art, the invention defined in claim 19 and the other claims would have been obvious to a person of ordinary skill well before the date the patentees

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[4] The '749 patent also discloses that ordinary pharmaceutical excipients may be used in making the hormone preparations. *See* '749 Patent, col. 9, ll. 10-14.

[5] *Compare* '749 Patent col. 1, ll. 9-26 *with* col. 4, ll. 50-59.

[6] In the estrogen/progestin combination as taught by the '749 patent, the ethinyl estradiol is 15-25 µg and the levonorgestrel is 50-125 µg. The subsequent 7-day period involves administering 10-15 µg of the estrogen. *See* '749 Patent, col. 6, ll. 8-59.

applied for their patent. Under 35 U.S.C. § 103(a), a patent is invalid as obvious if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." In *KSR Int'l Co. v. Teleflex Inc.*, the U.S. Supreme Court took an expansive view of this inquiry. Prior to *KSR*, the U.S. Court of Appeals for the Federal Circuit required an explicit teaching, suggestion, or motivation (the so-called "TSM" test) to combine the various references a challenger wished to rely upon to establish obviousness. *See Heidelberaer Druckmaschinen AG v. Hantscho Comm. Prods., Inc.*, 21 F.3d 1068, 1072 (Fed. Cir. 1994). In *KSR*, the Supreme Court rejected this "rigid approach," and held that "[t]he obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents." *KSR Int'l*, 550 U.S. at 419.

Under the "correct analysis," the Supreme Court said, "*any need or problem* known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420 (emphasis added). The Court expressly noted that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton"; thus, common sense is a crucial part of the obviousness inquiry: "Common sense teaches . . . that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.* at 420.

KSR reiterated that a combination of prior art elements must achieve more than a predictable result to be patentably nonobvious:

> [I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. . . . [A] court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.

Id. at 417.

Finally, contradicting earlier statements by the Federal Circuit, the Court instructed that obviousness may be established by showing that the combination of elements was "obvious to try." *Id.* at 421. According to the Court,

> [w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product *not of innovation* but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

Id. (emphasis added).

The application of these general principles to the prior art at issue here reinforces the obviousness of the '545 patent. The DE '017 Application and the '749 patent taught the benefits of adding unopposed estrogen following a prolonged period of administering a combination estrogen/progestin hormone such as was disclosed in the '032 patent. The method disclosed in the '545 patent yields only predictable results—indeed, the very results predicted by the prior art—by combining extended administration of a low-dose period combination pill with a period of unopposed estrogen.

Thus, it would have been obvious to a person of ordinary skill to modify the regimen of the '032 patent by adding the 7-day period of unopposed estrogen described in DE '017. More

specifically, taking the overlapping preferred ranges in the '032 prior patent and DE '017,[7] a person of ordinary skill would have understood those prior art patents at least to teach a method of female contraception involving:

> First administering for 84 days a combination of estrogen and progestin, followed by administering 7 days of unopposed estrogen, in which:
>
> - The estrogen dose administered as part of the combined oral contraceptive preparation is 15-20 μg of ethinyl estradiol;
> - The progestin dose is 70-125 μg of levonorgestrel;[8] and
> - The estrogen dose administered during the last 7 days is 10-15 μg of ethinyl estradiol.

As shown by the comparison below of the narrowest asserted claim of the '545 patent with these prior art teachings, the '032 patent and DE '017 thus made obvious the invention of claim 19 of the '545 patent:

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[7] The '032 patent and DE '017 expressly disclose the dosages set forth in the asserted claims of the '545 patent. Where a claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness. *Ricoh Co., Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325, 1331 (Fed. Cir. 2008); *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006) ("Where a claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness"); *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004); *In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997). This presumption can be rebutted only by showing that the prior art teaches away from the claimed range, or the range produces new and unexpected results. *Iron Grip*, 392 F.3d at 1322; *In re Geisler*, 116 F.3d at 1469.

[8] These active ingredients are formulated in a composition using standard pharmaceutical excipients. *See* DE '017, pg. 10, ll. 41-42.

Claim 19		Prior Art ('032 Prior Patent and DE '017)
A method of contraception in a female in need thereof, the method comprising administering to the female a dosage comprising a combination of estrogen and progestin for a period of 84 consecutive days, followed by administration of a dosage consisting essentially of estrogen for a period of 7 consecutive days,	→	A method of female contraception comprising first administering for 84 days a combination of estrogen and progestin, followed by administering for 7 days estrogen alone, in which
wherein the estrogen that is administered in combination with progestin for the period of 84 consecutive days is orally administered monophasicly in a daily amount of about 10 μg to about 30 μg of ethinyl estradiol,	→	the estrogen dose in the combination is 15-20 μg of ethinyl estradiol;
the estrogen that is administered for the period of 7 consecutive days is orally administered monophasicly in a daily amount of about 10 μg of ethinyl estradiol, and	→	the estrogen dose during the last 7 days is 10-15 μg of ethinyl estradiol; and
the progestin that is administered in combination with estrogen for the period of 84 consecutive days is orally administered monophasicly in a daily amount of about 50 μg to about 150 μg of levonorgestrel.	→	the progestin dose is 70-125 μg of levonorgestrel.

A similar analysis for claims 1, 2, 4-9, 15, 17, 18, and 20-21 produces a parallel result. *See generally Ormco Corp.*, 498 F.3d at 1319 (stating that if the narrower claim is obvious, the broader claim must also be obvious).

As explained above with respect to DE '017, it also would have been obvious to a person of ordinary skill to modify the regimen of the '032 patent by adding the 7-day period of unopposed estrogen described in the '749 patent. More specifically, taking the overlapping

preferred ranges in the '749 and '032 patents,[9] a person of ordinary skill would have understood those prior art patents at least to teach a method of female contraception involving:

> A method of female contraception comprising first administering for 84 days a combination of estrogen and progestin, followed by administering 7 days of unopposed estrogen, in which:
>
> - The estrogen dose administered as part of the combined oral contraceptive preparation is 15-20 μg of ethinyl estradiol;
> - The progestin dose is 70-125 μg of levonorgestrel;[10] and
> - The estrogen dose administered during the last 7 days is 10-15 μg of ethinyl estradiol.

This can be seen upon a comparison of the narrowest assertable independent claim (claim 19) in the '545 patent with the combined prior art teachings of the '032 and '749 prior patents:

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[9] The hormone dose ranges disclosed in the '032 and '749 patents expressly touch upon—and in some instances, encompass entirely—the dosages set forth in the '545 patent. Where a claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness. *Ricoh Co., Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325, 1331 (Fed. Cir. 2008); *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006) ("Where a claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness"); *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004); *In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997). This presumption can be rebutted only by showing that the prior art teaches away from the claimed range, or the range produces new and unexpected results. *Iron Grip*, 392 F.3d at 1322; *In re Geisler*, 116 F.3d at 1469.

[10] These active ingredients are formulated in a composition using standard pharmaceutical excipients. *See* '749 Patent col. 9, ll. 10-14.

Claim 19		Prior Art ('749 and '032 Prior Patents)
A method of contraception in a female in need thereof, the method comprising administering to the female a dosage comprising a combination of estrogen and progestin for a period of 84 consecutive days, followed by administration of a dosage consisting essentially of estrogen for a period of 7 consecutive days,	→	A method of female contraception comprising first administering for 84 days a combination of estrogen and progestin, followed by administering for 7 days estrogen alone, in which
wherein the estrogen that is administered in combination with progestin for the period of 84 consecutive days is orally administered monophasicly in a daily amount of about 10 μg to about 30 μg of ethinyl estradiol,	→	the estrogen dose in the combination is 15-20 μg of ethinyl estradiol;
the estrogen that is administered for the period of 7 consecutive days is orally administered monophasicly in a daily amount of about 10 μg of ethinyl estradiol, and	→	the estrogen dose during the last 7 days is 10-15 μg of ethinyl estradiol; and
the progestin that is administered in combination with estrogen for the period of 84 consecutive days is orally administered monophasicly in a daily amount of about 50 μg to about 150 μg of levonorgestrel.	→	the progestin dose is 70-125 μg of levonorgestrel.

A similar analysis for claims 1, 2, 4-9, 15, 17, 18, and 20-21 produces a parallel result.[11] *See generally Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1319 (Fed. Cir. 2007) (stating that if the narrower claim is obvious, the broader claim must also be obvious).[12] Accordingly, Lupin contends that the statutory presumption of validity has been overcome, and that claims 1, 2, 4-9, 15, and 17-21 are invalid as obvious under 35 U.S.C. § 103(a). The examiner allowed the '545 patent to issue apparently based upon the belief that the invention was novel due to "the discontinuation of progestin after the 81-89 days period." *See* Prosecution History for the '545 Patent's Parent Application (U.S. Patent No. 7,320,969). This statement shows that the examiner did not appreciate the teachings of the '749 patent or DE '017, which both expressly disclose the use of unopposed estrogen. Thus, while the '545 patent is presumed valid, the absence of real consideration by the examiner undermines the rationale for the presumption. *See KSR Int'l*, in which the Supreme Court commented on the impact of a failure to cite a pertinent prior art reference. 550 U.S. at 426 ("We need not reach the question whether the failure to disclose Asano during the prosecution of Engelgau voids the presumption of validity given to issued patents, for claim 4 is obvious despite the presumption. We nevertheless think it appropriate to note that the rationale underlying the presumption—that the PTO, in its expertise, has approved the claim—seems much diminished here.").[13]

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[11] A detailed claim chart for Lupin's invalidity contentions conforming to Pat. L. R. 3.3(c) is provided in Exhibit A.

[12] In *Ormco*, the Federal Circuit also found that packaging prior art products together into a kit did not establish novelty. *Id.* at 1309 ("Providing the devices to the patient in one package . . . is not a novel or patentable feature in light of the well-known practice of packaging items in the manner most convenient to the purchaser.").

[13] While the examiner's statement was made in connection with Pat. No. 7,320,969 (the parent application to the '545 patent), its claims are virtually identical to the pertinent claims of the '545 patent, there was no substantive discussion of the claims in the prosecution history of

B. Secondary considerations, to the extent they exist at all, cannot overcome the prima facie showing of obviousness.

As the Supreme Court stated in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966), so-called "secondary considerations" such as commercial success, unexpected results, long felt but unsolved needs, and failure of others are in some instances relevant to the obviousness inquiry. But although secondary considerations may influence an obviousness analysis, in this case they do not rebut the prima facie showing of obviousness. *See Newell Cos. Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1989).

The rationale for giving weight to these "secondary considerations" is that they provide objective evidence concerning the obviousness of the patented product or method. For that reason, secondary considerations are irrelevant to the nonobviousness of the claimed invention unless there is a connection—a nexus—between the secondary consideration and the unique or special aspects of the claimed invention. *See Ormco Corp. v. Align Technology, Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006) (*citing J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563 (Fed. Cir. 1997)).

For instance, in this case there are no unexpected results supporting nonobviousness. By definition, for an "unexpected" result to be relevant it must be unexpected. Here, the '749 patent touted eight benefits that it related to its combined administration of estrogen/progestin followed by the administration of unopposed estrogen, including less "break-through bleeding," increased compliance with the treatment, and fewer side effects such as headaches. *See* '749 Patent, col. 9, l. 33-col. 10, l. 4. Because all of the benefits ascribed to the methods claimed in the '545 patent

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the '545 patent, the examination of the '545 patent shortly followed that of the '969 patent, and the examination was conducted by the same examiner.

were already known in the prior art, this secondary consideration does not support nonobviousness.

Lupin also believes that sales of the LoSeasonique® product, administration of which may be covered by claims of the '545 patent, are not so substantial as to qualify as evidence of commercial success. Moreover, the absence of unexpected results vis-à-vis the prior art undermines any nexus between those sales and the putative invention, at least because the claimed invention provides no apparent new benefit to purchasers other than those benefits already described in the '749 patent. Thus, consumers do not purchase LoSeasonique® due to benefits that distinguished the claimed invention from the prior art; instead, those purchases are attributable either to benefits shared by the claimed invention and prior art, or to factors wholly unrelated to the claimed invention. Either way, there is no nexus between commercial sales of LoSeasonique® and the obviousness analysis. *Newell Cos. Inc.*, 864 F.2d at 768; *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 908 (Fed. Cir. 1985); *see Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376-77 (Fed. Cir. 2005) (nexus required). In addition, commercial success is not a relevant factor in determining obviousness if others are legally barred from practicing the invention. *See Merck & Co.*, 395 F.3d at 1376-77.

No other secondary consideration supports nonobviousness. Most are inapplicable, and the exception—copying—does not support a conclusion of nonobviousness because the framework established by the Hatch-Waxman Act[14] effectively requires identity of the active ingredients and of their dosage and administration. Even under the best of circumstances, "a showing of copying is only equivocal evidence of non-obviousness in the absence of more

[14] *See* Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355).

compelling objective indicia of other secondary considerations." *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1380 (Fed. Cir. 2000). Where, as here, copying is effectively mandated by statute, several courts have noted that copying—while perhaps not entirely irrelevant—is not compelling evidence of nonobviousness. *See, e.g.*, *Purdue Pharma Products L.P. v. Par Pharmaceutical, Inc.*, 642 F. Supp. 2d 329, 373-74 (D. Del. 2009) ("[A] showing of copying . . . is not compelling evidence of non-obviousness in the Hatch-Waxman context."); *Novartis Pharms. Corp. v. Teva Pharms. USA, Inc.*, No. 05-cv-1887 (DMC), 2009 WL 3754170, at *18 (D.N.J. Nov. 5, 2009) ("[T]he copying rationale in the context of an ANDA application has been recognized as weak, but not irrelevant."); *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, No. IP 99-38-C H/K, 2001 WL 1397304, at *14 (S.D. Ind. Oct. 29, 2001) ("To gain FDA approval, therefore, a company . . . must copy the patented invention as closely as possible. Small changes in chemical structure may have dramatic and unpredictable biological effects. To that extent, the evidence of copying adds a little weight against a finding of obviousness.").

In addition to the foregoing contentions, Lupin hereby incorporates—to the extent not inconsistent with the foregoing contentions—the invalidity contentions of defendants Watson and Mylan. Lupin also notes that a number of prior art references have been utilized by Watson in the litigation against Duramed relating to the parent '969 patent for the Seasonique® product. Based on Lupin's review of the publicly available pleadings from that litigation, as well as Lupin's own investigation, it is Lupin's belief that at least the following prior art references also support the obviousness of one or more claims of the '545 patent:

Kovacs et al., *A Trimonthly Regimen for Oral Contraceptives*, 19 British J. Family Planning 274 (1994).

Killick et al., Ovarian Activity in Women Taking an Oral Contraceptive Containing 20 µg Ethinyl Estradiol and 150 µg Desogestrel: Effects of Low Estrogen Doses During the Hormone-Free Interval, 179 Am. J. Obstret. Gynecol. S18-S24 (1998).

Dennerstein et al., Headache and Sex Hormone Therapy, 18 Headache 146 (1978).

Shortened Pill-Free Interval Delivered by New 20 mcg Pill, Contraceptive Tech. Update, July 1998, at 85-87.

Sulak et al., Extending the Duration of Active Oral Contraceptive Pills To Manage Hormone Withdrawal Symptoms, Obstetrics & Gynecology, Feb. 1997, at 179-83.

Sulak et al., Hormone Withdrawal Symptoms in Oral Contraceptive Users, Oral Contraceptive System, Feb. 2000, at 261-66.

Szarewski et al., Contraception: A User's Handbook, Oxford University Press, 1994.

U.S. Patent No. 3,502,772 (filed Oct. 16, 1967).

U.S. Patent No. 5,280,023 (filed Oct. 6, 1993).

III. CONDITIONAL CONTENTION REGARDING THE INVALIDITY OF CLAIMS 3 AND 22-24

These claims require that the estrogen that is administered for the period of 81 to 89 days be in a daily amount equivalent to "about 30 µg of ethinyl estradiol." Lupin's ANDA product contains 20 µg of ethinyl estradiol. As a result, for Lupin's ANDA product to infringe these claims, the limitation "about 30 µg of ethinyl estradiol" would have to be interpreted as encompassing a 20 µg amount.

Claim construction is the first step in an infringement analysis. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The second step is to compare the properly construed claims to the allegedly infringing product. *Id.* A court will find "literal infringement" only where *every* limitation of a patent claim is found in the accused product or device. *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931 (Fed. Cir. 1987) (*en banc*). As described above, the prior art squarely taught administration of 15-20

µg of ethinyl estradiol in the claimed method. In view of that prior art, these claims are invalid if the limitation of "about 30 µg" is construed to literally encompass administration of 20 µg of ethinyl estradiol. The more sensible interpretation is that "about 30 µg" involves some amount (significantly) above 20 µg. This construction not only preserves the claims' validity (to the extent that they are otherwise valid, which Lupin does not believe to be the case), but inevitably leads to the conclusion that Lupin's ANDA product would not literally infringe.

Nor would Lupin's ANDA product infringe under the doctrine of equivalents. Even if a product does not fall within the scope of the express language of a patent claim, direct infringement may be found if the patentee can establish that there is "equivalence" (i.e., no substantial difference) between the elements of the accused product and the claimed elements of the patented invention. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997). To determine whether such equivalence exists, the court may inquire "whether a product is substantially the same thing used substantially the same way to achieve substantially the same result" as the claimed invention. *Graver Tank Mfg. Co. v. Linde Air Prod. Co.*, 339 U.S. 605 (1950). But a patentee is precluded from capturing subject matter that could not have lawfully been claimed in light of the prior art. *Warner-Jenkinson*, 520 U.S. at 30. In the case of the '545 patent, the prior art prevents expansion of these claims to encompass 20 µg. *See Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 676, 684 (Fed. Cir. 1990) ("[A] patentee should not be able to obtain, under the doctrine of equivalents, coverage which he could not lawfully have obtained from the PTO by literal claims."). In sum, Lupin's product would not infringe claims 3 and 22-24 either literally under the doctrine of equivalents.

However, if claims 3 and 22-24 were construed contrary to the foregoing argument as encompassing a product contention at most 20 µg of ethinyl estradiol, then those claims would be invalid by the same reasoning as described above for other claims of the '545 patent that purport to encompass a dosing regimen involving 20 µg ethinyl estradiol in a combination pill.

IV. CLAIMS 10-14 AND 16 REQUIRE NO INVALIDITY CONTETNION BECAUSE NON-INFRINGEMENT IS SO CLEAR

Claim 10 and its dependent claims 11-14 require that an antidepressant be administered in combination with the dosage consisting essentially of estrogen. Lupin's ANDA product does not contain an antidepressant and would not infringe claims 10-14 literally or under the doctrine of equivalents. *See London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1539 (Fed. Cir. 1991) ("There is no infringement as a matter of law if a claim limitation is totally missing from the accused device."); *Dolly, Inc. v. Spalding & Evenflo Cos.*, 16 F.3d 394, 398 (Fed. Cir. 1990).

In addition, Lupin's ANDA product would not indirectly infringe claims 10-14. Lupin's labeling for its ANDA product does not instruct patients to take it in combination with an antidepressant for oral contraception, nor does Lupin expect substantially all patients taking its product to also be taking antidepressants. It is Lupin's belief that the sale and manufacture of its ANDA product will neither practice the method of claim 10, nor induce others or contribute to practice of that method. *See Micro Chem. Inc. v. Great Plains Chem. Co.*, 103 F.3d 1538 (Fed. Cir. 1997); *FMC Corp. v. Up-Right, Inc.*, 21 F.3d 1073 (Fed. Cir. 1994). Therefore, it is Lupin's belief that its product will not infringe claim 10 or its dependent claims.

A. Claim 16

Claim 16 requires transdermal administration of the estrogen and progestin hormones. Since Lupin's ANDA product is designed for oral use, and the product's label similarly instructs

patients to administer the pill orally, it is Lupin's belief that the sale or manufacture of its ANDA product will not directly or indirectly infringe claim 16 of the '545 patent. *See London v. Carson Pirie Scott & Co.*, 946 F.2d at 1539 (Fed. Cir. 1991).[15]

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[15] A detailed claim chart for Lupin's non-infringement contentions conforming to L. Pat. R. 3.6(d) is provided in Exhibit B.